

Remarks/Arguments

CLAIMS

Claims 48, 49 and 51-66 are currently pending in the application. In the Final Office Action of May 18, 2006, the Examiner rejects claims 48, 49 and 51-66 on anticipation grounds. Applicant amends claim 48 to further clarify the invention.

A. Applicant traverses the Examiner's rejection of claims 48, 49 and 51-66 under 35 U.S.C. §102(b) as being anticipated by EP 0 759 730 to *Burmeister*.

For an anticipation rejection to be proper, “[t]he identical invention must be shown in the as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (holding that anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”). Moreover, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (stating that anticipation can not be established by mere equivalents).

In the pending matter, despite the fact that European Patent No. EP 0 759 730 to *Burmeister* (hereinafter referred to as “*Burmeister*”) is devoid of any teaching of a stent with sensors, the Examiner nonetheless appears to maintain the position that *Burmeister* does teach of such a stent with sensors. The Examiner cites a passage in *Burmeister* (Column 11, Lines 35-37) to arrive at this position; the passage reads, “Radiopaque portions or coatings may be included on any parts of these stents as is known in the prior art.” From this short passage alone, the Examiner concludes that the *Burmeister* stent must somehow comprise a sensor element simply because the expansion of that stent “is *inherently detectable* with non-invasive radiographs, especially when using radiopaque portions or coatings” [Emphasis added]. (Page 3, Lines 17-18 of the Final Office Action dated October 5, 2005).

Applicant respectfully disagrees with the Examiner's unconventionally broad interpretation of *Burmeister*. Applicant notes that nowhere in *Burmeister* is there a direct

reference to the word “sensor” or a word with an equivalent meaning. (Applicant welcomes the Examiner to specifically point out where in *Burmeister* is there a direct reference to the term “sensor”.) Under the Examiner’s unconventional interpretation of the term “sensor” (i.e., anything that is “inherently detectable” qualifies as a sensor), almost any object under the sun would qualify as a sensor. Based on the Examiner’s interpretation, even a human person could theoretically qualify as a “pressure sensor” because a human person would respond to a punch (pressure stimulus) to his stomach by wincing in pain (response) in a manner that would be visible and detectable to a casual observer. Similarly, under the Examiner’s definition of a sensor, even a door hinge would qualify as a “pressure sensor” because a door hinge’s structural configuration (response), is dependent on the opening (pressure stimulus) or closing (pressure stimulus) of a door, all of which can be detected by and visible to a casual observer.

Needless to say, those skilled in the art would not interpret a door hinge or a human being as a sensor. Likewise, those skilled in the art would not interpret the *Burmeister* stent as having sensors. Contrary to the Examiner’s suggestion, mere possession of “radiopaque portions or coatings” would not automatically render an object (e.g., stent) as a sensor. In contrast to the Examiner’s unconventional definition of the term “sensor” (i.e., anything that is “inherently detectable”), Webster’s Online Dictionary <<http://www.m-w.com>> defines a sensor as “a *device* that responds to a physical stimulus (as heat, light, sound, pressure, magnetism, or a particular motion) and *transmits a resulting impulse* (as for measurement or operating a control)” [Emphasis added]. As understood by those skilled in the art, “radiopaque portions or coatings” do not constitute as a *device*, nor do they *transmit a resulting impulse*. Thus, the “radiopaque portions or coatings” described in *Burmeister* do not constitute a sensor, as commonly understood by those skilled in the art, nor would their mere presence on an object render the object into becoming a sensor. Applicant kindly welcomes the Examiner to cite a specific credible reference (e.g., journal publication or patent document) that specifically (1) defines a radiopaque coating as being a sensor; or (2) teaches that mere presence of a radiopaque coating on an object automatically renders said object into becoming a sensor because said object would be “*inherently detectable* with non-invasive radiographs, especially

when using radiopaque portions or coatings” (i.e., the Examiner’s personal unconventional standard for qualifying an object as a sensor).

As recognized by those skilled in the art, the Examiner’s anticipation rejection of Applicant’s invention based on *Burmeister*’s teaching of stents, with “radiopaque portions or coatings,” is illogical for the simple reason that Applicant’s sensors, as described in the pending application, and “radiopaque portions or coatings” on/in a stent, as taught in *Burmeister*, do not represent analogous arts. Simply put, Applicant’s sensors, which employ cantilevers, are *structurally* and *functionally* different from *Burmeister*’s teaching of “radiopaque portions or coatings.”

With reference to Paragraph 6 of *Burmeister*, Applicant notes that *Burmeister*’s stent “allows for initial self-expansion and subsequent deformation to a *final* enlarged diameter in the body” [Emphasis added]. In other words, after implantation, *Burmeister*’s stent goes into a passive state, where the stent’s physical properties theoretically remain constant and are not intended to react/respond to internal conditions of the body, let alone externally applied energy/stimulus, as recited in pending claim 48. Thus, after implantation and initial expansion, *Burmeister*’s stent does not undergo any additional conformational changes within the device. Accordingly, *Burmeister*’s stent can not even function as a sensor.

By contrast, Applicant’s invention does incorporate a sensor (one that is recognized by those skilled in the art to be a sensor). After implantation into the body, the claimed stent eventually reaches an equilibrium condition, just like *Burmeister*’s stent. Unlike *Burmeister*’s stent, however, the claimed stent after reaching the equilibrium condition, will not remain in a passive state. Rather, the claimed stent’s sensors will detect changes in the energy state proximate the claimed stent and respond to the internal equilibrium environment (e.g., blood pressure, blood temperature, plaque growth or state of endothelialization). What is more, the claimed stent’s sensors will also respond to externally applied energy. The externally applied energy/stimulus may be exogenous energy stimulus such as externally applied temperatures, pressure, microwave, ultrasound, RF, ultraviolet, infrared, magnetic resonance, x-rays, beta or gamma irradiation. In essence, the claimed stent’s sensors selectively detect changes in energy

states after being implanted in the in vivo environment and will respond to energy state changes.

Burmeister fails to teach any of these claimed features, whether the capability to respond to internal energy proximate the stent or the capability to respond to externally applied energy. As discussed above, *Burmeister*'s stent is not intended to undergo conformational changes after implantation. Thus, it would be clearly understood by those skilled in the art that *Burmeister* does not teach of incorporating sensors into a stent.

Applicant does acknowledge that hypothetically the Examiner's rejection would have been appropriate had claim 48 omitted references to sensors and instead read as follows:

48. An implantable sensor device having a plurality of structural elements capable of expanding within an anatomical passageway comprising first and second structural elements ~~where at least some of the plurality of first structural elements further comprise at least one first sensor element and where at least some of the plurality of second structural elements further comprise at least one second sensor element,~~ both sensors which selectively detect an energy stimulus and responds to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member.

However, in contrast to the above hypothetical claim, pending claim 48 does make specific references to sensors. Even so, the Examiner appears to still ignore the fact that the structural elements and the sensor elements of the claimed invention are separate and distinctive elements.

Furthermore, even assuming *arguendo* that *Burmeister*'s "radiopaque portions or coatings" somehow do constitute as sensors -- a position that Applicant strongly disagrees with -- the Examiner's anticipation rejection would still be improper because *Burmeister* would not qualify as an enabling prior art reference with regard to Applicant's pending application. Courts have consistently held that for a prior art reference to anticipate a claimed invention, the prior art reference must be enabling. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1354 (Fed. Cir. 200) (stating that "a claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosure cited as prior art are not enabled ... a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if the disclosure fails to 'enable

one of skill in the art' to reduce the disclosed invention to practice' ” and quoting from *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1962)).

Moreover, according to the Federal Circuit, “[t]o serve as an anticipating reference, the reference *must enable that which it is asserted to anticipate*” [Emphasis added]. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. And Research*. 345 F.3d 1051, 1054 (Fed. Cir. 2003). In other words, in order “[t]o anticipate a claim, a reference must disclose every element of the challenged claim and *enable one skilled in the art to make the anticipating subject matter*” [Emphasis added]. *PPG Indus. V. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

In the pending matter, *Burmeister* does not disclose sensor elements, let alone enable those skilled in the art to produce sensors that “selectively detect an energy stimulus and responds to the detection of the energy stimulus *by altering the geometry or conformational profile of the device body member*”[Emphasis added], as recited in claim 48. Simply put, Applicant submits that *Burmeister's* brief suggestion of including “radiopaque portions or coatings” in parts of stents, would not enable those skilled in the art to develop stents with sensors that “selectively detect an energy stimulus and responds to the detection of the energy stimulus *by altering the geometry or conformational profile of the device body member.* ”

Thus, for the reasons stated above, claims 48, 49 and 51-66 are distinguished from the prior art cited and of record. Accordingly, Applicant kindly requests that the Examiner withdraw the anticipation of claims 48, 49 and 51-66.

B. Amended claim 48 is further distinguished from *Burmeister*.

Applicant further clarifies the invention by amending claim 48 to recite, “wherein the first and second sensor elements are operatively associated with a first structural element and a second structural element, respectively.” Applicant submits that the aforementioned amendment further highlights the differences between *Burmeister's* stent and the claimed invention -- namely that Applicant's claimed sensor elements are separate and distinctive from the claimed structural elements, whereas *Burmeister* does not make any reference to “sensors,” let alone teach of Applicants' stent arrangement with regard to sensors and structural members.

Applicant submits that the amendment does not present new issues because the amendment merely clarifies an existing subject matter. Accordingly, Applicant submits that claim 48 and claims dependent therefrom (i.e., claims 49 and claims 51-66) are further distinguished from the cited prior art of record.

For the reasons stated above, Applicant submits that the Examiner's anticipation rejection is improper and kindly requests that the rejection be withdrawn.

Summary:

The Examiner's rejections of claims 48, 49 and 51-66 have been obviated by the above amendments to the claims. Accordingly, Applicant submits that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited. If any questions remain that may be resolved in a telephone interview, Applicant asks the Examiner to contact the undersigned.

The amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Response is being concurrently filed with an Amendment Transmittal Letter including a fee calculation sheet, any applicable Request for Extension, and fee calculations. The Director is authorized to deduct any additional expenses from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Lee', with a stylized flourish extending to the right.

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